

REMARKS

In the Office Action, claims 1 and 3-28 are rejected under 35 U.S.C. § 102, or in the alternative, under 35 U.S.C. § 103. The Patent Office essentially asserts that this reference discloses or suggests each and every feature of the claimed invention. Applicants believe that the anticipation and obviousness rejections are improper at least for the reasons set forth below.

Of the pending claims at issue, claims 1, 12 and 21 are the sole independent claims. Claim 1 relates to a dialyzer inlet header that includes a body designed to be attached to an end of a dialyzer; an inlet channel that provides fluid communication from an exterior of the dialyzer to an interior of the dialyzer wherein the inlet channel defines a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer. The dialyzer inlet header further includes at least one member for modifying the fluid flow path of fluid as it exits the inlet channel wherein the modifying member includes a curved vane that extends from a portion of the body.

Independent claim 12 relates to a dialyzer. The dialyzer includes a body; a fiber bundle located in an interior of the body; a blood inlet located at a first end of the body that includes a fluid flow channel that causes blood to flow in an axial direction with respect to the fiber bundle; and a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

Independent claim 21 relates to a dialyzer header. The dialyzer header includes a body member that has an inlet channel for providing fluid communication from an exterior to an interior of the header wherein the inlet channel defines a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached. The body member of the dialyzer header includes a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

Applicants have discovered that the improved header design of the present invention can provide and improve flow of blood into the interior of the dialyzer and specifically to the fiber bundle. This eliminates, or at least substantially reduces, the zones of low flow thereby reducing the potential for clotting while improving the ability to rinse the header of blood. See, Specification, page 2, lines 15-20.

With respect to the anticipation rejection, clearly this rejection is improper. At the outset, it is improper for the Patent Office to assert the anticipation rejection and in the alternative assert

an obviousness rejection with respect to the same reference, namely DE 3435883. Indeed, the Patent Office clearly asserts an obviousness position rather than anticipation. For example, the Patent Office alleges that the member, including curved vanes being extended from or integral with the body is "merely a matter of obvious engineering choice." See, Office Action, page 2. Further, the Patent Office alleges that evidence is required to demonstrate an unexpected substantial improvement over the prior art. See, Office Action, page 3. Clearly, this demonstrates an intent on the part of the Patent Office to reject the claimed invention under an obviousness standard rather than anticipation. Thus, at least the anticipation rejection should be withdrawn for these reasons.

Even assuming that the Examiner can reject the claimed invention under anticipation and in the alternative under an obviousness standard, the cited art still fails to anticipate and render obvious the claimed invention. For example, the cited reference fails to disclose a modifying member that extends from and/or is integral to a body of the dialyzer header as required by the claimed invention. Indeed, the Patent Office essentially admits same as disclosed on pages 2 and 3 of the Office Action. Thus, DE 3435883 fails to anticipate the claimed invention for at least these reasons.

Further, Applicants believe that the Patent Office has improperly modified the cited reference to arrive at the claimed invention. At the outset, the dialyzer header as disclosed in the cited reference is structurally different than the claimed dialyzer header as essentially admitted by the Patent Office and discussed above. Indeed, the primary focus of the cited reference relates to a plate (46) attached to and spaced apart from a closure cap (24). This allows liquid to flow radially outward in the upper section and through gaps or holes (66) spaced between a periphery of the plate (46) and the cap (24). See, DE 3435883, Abstract, Figures 1 and 2. Thus, the flat plate (46) has a pronounced influence on the fluid flow as disclosed in DE 3435883.

Clearly, this is distinguishable from a dialyzer header that includes a modifying member that extends from and/or is integral thereto as required by the claimed invention. With this construction, the fluid flow path is modified to impart a circular motion to fluid in contact with the modifying member as it enters the interior of the header. The modifying member can include, for example, curved vanes and curved channels to facilitate the circular flow of fluid. As previously discussed, this type of flow can eliminate, or at least substantially reduce, the

zones of low flow and thereby reducing the potential for clotting while improving the ability to rinse the header of blood. Thus, Applicants believe that one skilled in the art would consider the cited reference and the claimed invention to be structurally and functionally different.

Based on at least these noted differences, Applicants believe that the cited reference is deficient with respect to the claimed invention. Therefore, Applicants believe that the cited reference fails to anticipate and render obvious the claimed invention.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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